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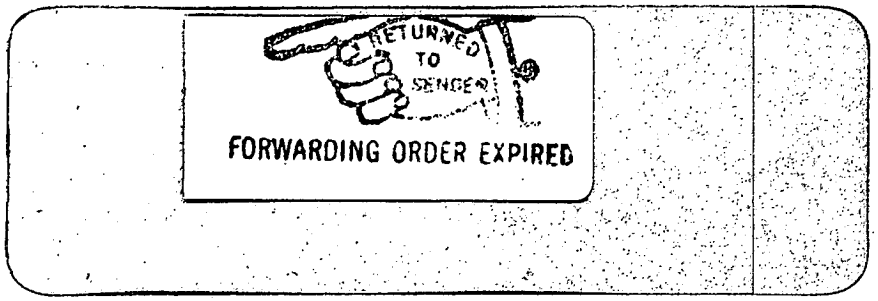

1648

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,185	10/18/2001	Johan Adriaan Marc Grooten	DECLE1.001DV1	4839

7590 10/18/2005

EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/18/2005

KNOBBE, MARTENS, OLSON & BEAR, LLP
16 th Floor
620 Newport Center Dr.
Newport Beach, CA 92660

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,185	GROOTEN ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed July 26, 2005 in response to the Office Action of April 26, 2005 is acknowledged and has been entered. Claims 14 and 18 have been cancelled. Claims 9 and 10 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 1 and 9 a under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing the survival of memory T cells after exposure to an antigen with IL-15, does not reasonably provide enablement for treating an immune deficiency disease (such as HIV) by administering anti-IL15-antibodies **is withdrawn** in view of applicants amendments to the claims limiting the treatment to autoimmune disease.

Claim Rejections - 35 USC § 102

The rejection of claims 9 and 10 under 35 U.S.C. 102(e) as being anticipated by Grabstein et al. (U.S. Pat. No. 5,795,966) **is maintained** for reasons of record.

Applicants have amended the claims to now recite that the anti-IL-15 antibody administration occurs "when the immune response is subsiding." The instant invention is drawn to a method of treating a mammal by administering an anti-IL-15 antibody for the treatment of autoimmune disease.

Applicants' arguments are that the reference does not teach administration of the anti-IL-15 antibody after the immune response is subsiding. In response, the reference of Grabstein et al. discloses the administration of anti-IL-15 antibodies yet is silent regarding the timing of administration. The reference does disclose that the antagonist will be administered during the time period that the cells responsible for the disease condition are expressing IL-15 on their surface. (see column 12, lines 16-51). One of ordinary skill in the art would recognize that the condition of expressing IL-15 on their cell surface will be present before, during and after an immune response. The condition of expressing IL-15 on their cell surface includes all periods during which the disease causing cells are expressing IL-15. Thus the treatment methods using the IL-15 antagonist (anti-IL-15 antibody) includes treatment after the immune response has waned. For the above reasons applicants arguments are not persuasive.

Grabstein et al. discloses the use antagonists, anti-IL-15 antibodies, in a method of treating a disease or condition in which a reduction in IL-15 activity on T cells is desired. Such diseases include organ transplant rejection, graft versus host disease, autoimmune disease, rheumatoid arthritis, inflammatory bowel disease, dermatologic disorders, insulin-dependent diabetes mellitus, ocular disorders and idiopathic nephrotic syndrome/idiopathic membranous nephropathy (see column 3, lines 5-35). The reference discloses antibodies against IL-15 see claims. Therefore, the instant invention is anticipated by Grabstein et al.

New rejections in view of applicants' amendments:

Claim Rejections - 35 USC § 112

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims have been amended to "when the auto-immune response is subsiding in order to suppress formation of memory cells of the immune system." There is no written description for administering the antibody to treat an autoimmune after the immune response has subsided. The prior claims 14 and 18 made reference to "treatments before during or after transplantation" or "treatment before during or after vaccination." Neither the claims nor the specification made any indication regarding the timing of the administration of the antibody in reference to the treatment of autoimmune disease. Therefore, the instant limitation lacks written description for the timing of the treatment of autoimmune disease with an antibody.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims require the administration of the anti IL-15 antibody at a point "when the auto-immune response is subsiding in order to suppress formation of memory cells of the immune system." It is not clear what marks the point "when the auto-immune response is subsiding" one having ordinary skill in the art would not know what is intended by this limitation. How is this point defined? How is this point measured?

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In this instance the title is not commensurate in scope with the claims.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 10/17/05